UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY
CAMDEN VICINAGE

IN RE: VALSARTAN, LOSARTAN, AND IRBESARTAN PRODUCTS LIABILITY LITIGATION	MDL No. 2875 Honorable Robert B. Kugler, District Court Judge Honorable Karen Williams Magistrate Judge Honorable Thomas Vanaskie (Ret.), Special Discovery Master

THE ZHP PARTIES' REPLY SUPPORTING THEIR MOTION TO SEAL

I. INTRODUCTION

Plaintiffs' brief in opposition ("Opposition") to the ZHP Parties'[1] Motion to Seal (the "Motion to Seal" or "Motion") (Dkt. 859) fails to prove that the challenged documents identified in the Motion (the "Challenged Documents") are improperly designated as confidential under the Protective Order, or that Plaintiffs would be prejudiced as a result of their remaining confidential.

Although Plaintiffs mischaracterize the Challenged Documents as routine business communications, in fact, the documents contain the ZHP Parties' highly sensitive and proprietary information, which should not be exposed to their direct competitors in this lawsuit. As the Third Circuit has repeatedly confirmed, documents containing confidential and proprietary information may be properly sealed to protect a party's competitive interests. *See Littlejohn v. BIC Corp.*, 851 F.2d 673, 678 (3d Cir. 1988) (citing *Nixon v. Warner Comm'n*, 435 U.S. 589, 598 (1978); *see also Mylan Inc. v. SmithKline Beecham Corp.*, 723 F.3d 413, 415 n3 (3d Cir. 2013) (finding good cause to seal where doing so would protect the parties "confidential proprietary business and competitive interests."). Nor does the Court's recent decision concerning Torrent Pharmaceuticals alter that conclusion where the

[1] The ZHP Parties have previously been defined in the Motion as Defendants Zhejiang Huahai Pharmaceutical Co., Ltd. ("ZHP"), Prinston Pharmaceutical Inc. ("Prinston"), Huahai U.S. Inc. ("Huahai U.S.") and Solco Healthcare US, LLC ("Solco"). *See* Mot. at 1.

documents designated by Torrent, unlike the Challenged Documents, did not discuss proprietary procedures or policies.

Although Plaintiffs maintain that the public has a right to be informed about this case as a matter of public health, Plaintiffs have not articulated how any of the Challenged Documents relate to, let alone inform, public health. Many of the Challenged Documents concern drugs that were never available for sale in the United States. Moreover, any valsartan manufactured by the ZHP Parties that was for sale in the United States was recalled two years ago, and poses no potential risk to any individual.

Nor have Plaintiffs articulated any prejudice in adhering to the Protective Order. Plaintiffs can use the designated documents in deposing witnesses. Additionally, maintaining the confidentiality of the challenged documents will not impede any individuals from filing suit, as any relevant facts are publicly available in the Master Complaints, and the U.S. Food & Drug Administration ("FDA") has issued numerous announcements and updates about its investigation into the alleged impurities.

Rather, Plaintiffs' repeated and unsubstantiated confidentiality challenges appear designed to obtain a tactical advantage over the ZHP Parties and the other manufacturer defendants. Rather than raise confidentiality challenges efficiently after the end of the fact deposition period, Plaintiffs are attempting to distract the

ZHP Parties from time-sensitive discovery issues by forcing them to file successive sealing motions, wasting the ZHP Parties' time, and the Court's resources.

Because Plaintiffs cannot demonstrate that Challenged Documents are improperly designated or show any undue burden as a result of the Challenged Documents remaining confidential, the Court should reject Plaintiffs' challenges and grant the ZHP Parties' Motion to Seal.

II. ARGUMENT

A. The ZHP Parties Have Demonstrated Particularized Harm Resulting from the Disclosure of the Challenged Documents

The Third Circuit has repeatedly recognized the need to seal documents where court documents "are sources of business information that might harm a litigant's competitive standing." *See Littlejohn*, 851 F.2d at 678; *see also LEAP Sys., Inc. v. MoneyTrax, Inc.*, 638 F.3d 216, 218-19 (3d Cir. 2011) (finding interest in maintaining confidentiality of sensitive business information legitimate); *Mars, Inc. v. JCM Am. Corp.*, No. 1:05-cv-3165, 2007 WL 496816, at * 2 (D.N.J. 2007) (stating, "[c]ourts generally protect materials containing trade secrets or other confidential research, development, or commercial information to prevent harm to a litigant's standing in the marketplace.").

As set forth in the Motion and supporting Declarations, the ZHP Parties have demonstrated that they will suffer particularized harm if the Challenged Documents were disclosed to the public. This risk is all the more compelling in light of the ZHP

Parties' current competitive disadvantage as a result of the FDA import ban. While Plaintiffs downplay the information contained in the Challenged Documents as routine business communications or technical issues, *see* Opp. at 1-2 (Dkt. 988), the Challenged Documents contain detailed business information and internal discussions regarding the ZHP Parties' processes for evaluating and responding to customer concerns or regulatory issues. Nor is this an issue of mere embarrassment—the Challenged Documents reflect the ZHP Parties' ongoing efforts to operate in an intensely competitive market.

For example, with respect to the Category 1 Documents, disclosure would provide direct competitors of the ZHP Parties insight into their proprietary research, development, proposed process changes, and technical information related to the components and formulation of its APIs and drug products. Valuable business and trade secrets created at substantial expense by the ZHP Parties would be lost, while their competitors would gain not only the benefit of the ZHP Parties' efforts, but the ability to implement the ZHP Parties' information while the ZHP Parties are competitively constrained as a result of the FDA's current import ban.

Similarly, the Category 2 FDA establishment inspection reports evaluate the ZHP Parties' facilities' readiness to commercially manufacture numerous APIs and drug products, including those not at issue in this litigation. They detail manufacturing operations; standard operating procedures; proprietary training

programs; supplier qualification procedures; process validation reports; deviation investigation procedures; and analytical testing methods relating to numerous APIs and drug products, very few of which are at issue in this litigation. Allowing such documents to be disclosed to almost all of the ZHP Parties' competitors would be tantamount to turning over a guidebook to the ZHP Parties' manufacturing facilities, procedures and protocols. The Protective Order was entered to avert such widespread disclosure of confidential information; yet this is precisely what Plaintiffs seek.

Finally, the Category 3 communications contain non-public, commercially sensitive information shared with the ZHP Parties' customers. Disclosure without prior authorization from the customers with whom the communications were made, would cause significant competitive harm by forcing the ZHP Parties to (1) disregard the express intention of their customers, or (2) breach outstanding confidentiality agreements with their customers, thus jeopardizing customer relationships, and risking significant financial harm in the form of litigation costs and damages. This injury is particularly needless since many of the challenged communications discuss non-U.S. DMF grade valsartan (i.e., valsartan that has not and could not be sold in the United States), which is not a product at issue in this litigation.

Plaintiffs attempt to conflate the five challenged documents in the Torrent decision with the twenty-nine Challenged Documents at issue here. *See* Opp. at 7.

But Plaintiffs' comparisons fail where the documents at issue in Torrent consisted of discrete business communications, all of which explicitly address the NDMA contamination directly at issue in this litigation. *See In re Valsartan N-Nitrosodimethylamine (NDMA), Losartan, and Irebesartan Prods. Liab. Litig.*, 2021 WL 75258, at *12 (D.N.J. Jan. 8, 2021) (summarizing the emails as discussing Torrent's manufacturer/API sources distributed products in the United States that use the suspected synthesis that caused the NDMA impurity, NDMA impurity testing, notifications regarding the presence of trace amounts of NDMA, and exposure limits). Conversely, many of the Challenged Documents here address drug products or API not relevant to the litigation here, or underlying proprietary manufacturing processes or systems much broader than those at issue in Torrent. Nor did Torrent articulate how disclosure of the challenged documents would cause significant, specific competitive or financial harm. *See id*. at *15. By contrast, the ZHP parties have submitted no fewer than seven declarations from ZHP custodians, detailing how the disclosure of the information described in each of the Challenged Documents would harm the ZHP Parties' ability to compete. *See* Declaration of Kelly Bonner dated February 20, 2021 (Dkt. 859-3), Exs. B-H.

B. Plaintiffs Do Not Articulate How The Challenged Documents Relate To, Let Alone Inform Public Health and Safety Concerns

Plaintiffs premise their Opposition on the vague assertion that the public has a general right to see information relating to public health and safety. *See* Opp. at 2.

But Plaintiffs have not articulated how the Challenged Documents relate to, let alone inform public health concerns. Nor have they explained how that relation outweighs the ZHP Parties' interest in safeguarding its proprietary commercial information. *See In re Avandia Mktg., Sales Practices & Prod. Liab. Litig*, 924 F.3d 662, 671-72 (3d Cir. 2019) (advising that "various factors" including, "whether confidentiality is being sought over information important to public health and safety" should be considered as part of a balancing test.) Plaintiffs do not allege, for example, that the Challenged Documents contain misrepresentations regarding research findings or safety data, or falsified data or misleading claims. Nor do Plaintiffs allege that the Challenged Documents summarize, contextualize, or analyze any alleged NDMA contamination that would provide a comprehensive overview capable of informing the public.

At most, Plaintiffs allege that the Challenged Documents allow ZHP to "monopolize the information needed for a true understanding of the nitrosamine contamination of its valsartan." *See* Opp. at 8. But Plaintiffs do not identify any information in the Challenged Documents that would enable a "true understanding," or for whom this understanding is intended. Dissemination of the Challenged Documents will not inform the public as to current risks of nitrosamine contamination, nor will they provide a coherent understanding of the issues to any lay individuals sifting through millions of pages. This is especially true where the

drug has been recalled for almost three years, so no consumer is at risk of physical injury by the disclosure or non-disclosure of any information—let alone proprietary and competitively sensitive information for which Plaintiffs have not shown a need-- and where the FDA has provided information regarding the valsartan recalls and the FDA's investigation into the alleged nitrosamine impurities on its website. *See e.g.*, *FDA Statement on FDA's ongoing investigation into valsartan impurities and recalls and an update on FDA's current findings* (Aug. 30, 2018), https://www.fda.gov/news-events/press-announcements/fda-statement-fdas-ongoing-investigation-valsartan-impurities-and-recalls-and-update-fdas-current; *FDA Updates and Press Announcements on Angiotensin II Receptor Blocker (ARB) Recalls (Vasartan, Losartan, and Irbesartan)* (last updated Nov. 13, 2019), https://www.fda.gov/drugs/drug-safety-and-availability/fda-updates-and-press-announcements-angiotensin-ii-receptor-blocker-arb-recalls-valsartan-losartan.

C. Plaintiffs' Confidentiality Challenges Disregard the Protective Order to Seek a Tactical Advantage

As the Court is aware, this litigation gives rise to unique concerns with respect to the protection of commercially sensitive information. There are approximately 50 defendants, many of whom are direct competitors, whose discovery documents reveal commercially sensitive information.

In recognition of Defendants' concerns, the parties agreed to the Protective Order, which establishes a mechanism for producing parties to safeguard their

information. The ZHP Parties have produced approximately three million pages worth of documents in reliance on the Protective Order. But since November 2020, Plaintiffs have issued a series of unsubstantiated confidentiality challenges. For example:

- On November 18, 2020, Plaintiffs challenged the confidentiality designations of seven documents. *See* Declaration of Kelly Bonner dated March 8, 2021 ("Bonner Decl.") at ¶ 3, attaching letter from Adam Slater dated November 18, 2020 as **Exhibit A**.[2]

- On November 23, 2020, Plaintiffs' counsel challenged the confidentiality of five documents they wished to attach as exhibits to the November 24, 2020 Case Management Conference agenda letter (Dkt. 638), claiming "[t]here is nothing about the documents that

[2] Plaintiffs allege that the ZHP Parties waived confidentiality as to the documents identified in their letter dated November 18, 2020, to which the ZHP Parties responded on December 8, 2020. *See* Opp. at 1. Plaintiffs omit that the ZHP Parties responded on December 8, 2020, readily agreeing to de-designate five of the seven challenged documents as inadvertently designated, and maintained their designations as to only two of the seven documents identified, ZHP00406066 and PRINSTON00156783. These documents were (and still are) subject to an ongoing meet and confer process pursuant to Section 20(a) Protective Order rather than the sealing process described in Section 31. On February 1, 2021, counsel for the ZHP Parties proposed an extension of time to continue conferring and if necessary, file an omnibus sealing motion to address all challenged document. *See* Bonner Decl. ¶ 6, Ex. D. However, Plaintiffs' counsel rejected that proposal and advised the ZHP Parties to move to seal. *See id*. The ZHP Parties maintain that ZHP00406066 and PRINSTON00156783 are still subject to an ongoing meet and confer process with Plaintiffs, which the ZHP Parties are happy to renew following the Court's decision on the Motion to Seal as to avoid unnecessary and duplicative motion practice. Alternatively, ZHP Parties request that this Court permit the ZHP Parties to propose redacted versions or file a supplemental sealing motion or as to only ZHP00406066 and PRINSTON00156783, in keeping with the pragmatic approach articulated in the Protective Order.

justifies treatment as confidential under the protective order, especially in light of the public health interests involved." *See* Bonner Decl. ¶ 4, attaching emails between Christopher Geddis and Jessica Priselac dated November 23, 2020, as **Exhibit B**. When counsel for the ZHP Parties advised Plaintiffs that they failed to adhere to the procedures set forth in the Protective Order as to challenging the designations, or provide the ZHP Parties with sufficient time to evaluate their request, Plaintiffs' counsel triggered the defined period under Section 31 of the Protective Order by which to move to seal. *See id*.

- On December 21, 2020—one week later—Plaintiffs' counsel advised that they intended to challenge the confidentiality of twenty-three (23) designated documents they wished to attached as exhibits to the December 22, 2020 Case Management Conference agenda letter (Dkt. 685). *See* Bonner Decl. ¶ 5, attaching email communications between Christopher Geddis and Jessica Priselac dated December 21, 2020 as **Exhibit C**. Again, Plaintiffs asserted a blanket challenge, claiming, verbatim to their November 23 email, "[t]here is nothing about the documents that justifies treatment as confidential under the protective order, especially in light of the public health interests involved." *See id*.[3]

- In follow up communications with Plaintiffs, the ZHP Parties sought to allow the parties to attempt to reach an amicable global resolution to the confidentiality disputes. Counsel met and conferred on December 21, 2021, during which Plaintiffs agreed to provide Defendants with a proposal for criteria to downgrade the documents in light of the alleged public health concerns. Counsel met and conferred on again on January

[3] Plaintiffs contend that because the ZHP Parties moved to seal only the documents attached as exhibits to Mr. Slater's Case Management letter dated December 21, 2020 (Dkt. 685) and not the letter itself, the ZHP Parties have waived confidentiality as to the exhibits. *See* Opp. at 1. Mr. Slater's letter describes the exhibits opaquely, and redacts any confidential information; consequently, Mr. Slater's letter did not pose the same level of competitive risk as the exhibits. Assuming the Court agrees with Plaintiffs, the ZHP Parties would request that this Court to preserve the redactions in Adam's letter as the least restrictive means of balancing public access with the protection of confidential information, and in keeping with the pragmatic approach articulated in the Protective Order.

8, 2021, during which Plaintiffs' counsel was unable to propose the requested categories. Counsel met and conferred on January 27, 2021, at which time the parties discussed potentially agreeing upon redacted versions of the documents at issue in order to avoid successive motion practice.

- On February 1, 2021, Plaintiffs challenged the confidentiality designations of an additional forty three designated documents that they intended to file as exhibits to their opposition to the ZHP Parties' motion for a protective order. *See* Bonner Decl. ¶ 5, attaching an email from Christopher Geddis dated February 1, 2020 as **Exhibit D**. Again, Plaintiffs asserted a blanket challenge to all of the documents on the basis of an alleged public health interest. *See id.*

- On February 1, counsel for the ZHP Parties requested an extension to the February 5 deadline to address all challenges in one motion, giving the overlapping documents at issue and to avoid duplicative motions. *See* Bonner Decl. ¶ 6, attaching emails between Kelly Bonner and Cheryl Calderon dated February 1-2, 2020 as **Exhibit E**. On February 2, 2020, Plaintiffs' counsel advised to "just file your motion to seal," curtailing further discussions and necessitating the instant Motion. *See id*.

Since the ZHP Parties filed the Motion to Seal on February 5, 2021, Plaintiffs have issued a series of blanket challenges to the ZHP Parties' designations to excerpts of deposition transcripts and exhibits, each triggering another meet and confer process or obligation to prepare and file a motion to seal—no matter how duplicative or burdensome. When the ZHP Parties advised Plaintiffs that it made sense to wait until the Court issued an order on the Motion to Seal, providing some clarity on the issue, Plaintiffs advised that they did not agree to stay or suspend the time periods set forth in the Protective Order for filing a motion to seal, and urged

the ZHP Parties to file yet another motion on this issue. *See* Bonner Decl. ¶ 6, Ex. D.

Plaintiffs' continued refusal to approach these issues in a global manner, and insistence that the ZHP Parties burden the Court with successive motions to seal that raise the same arguments, is yet another example of their failure to make a good faith effort to try to resolve these issues amicably before forcing the ZHP Parties to engage in motion practice.

In addition, Plaintiffs have not articulated any prejudice whatsoever as a result of adhering to the ZHP Party's designations under the Protective Order. As previously noted, Plaintiffs can freely use the designated documents in deposing witnesses (*see* Dkt 139 at ¶ 29), and maintaining the confidentiality of the challenged documents will not impede any individuals from filing suit, as the information that would inform an individual's decision to file suite are publicly available, including in the Plaintiffs' Master Complaints. *See* Master Compls. (Dkt. 122, 123, 398).

Meanwhile, Plaintiffs' challenges have far-reaching implications for not only the ZHP Parties, but for the fifty other Defendants in this litigation who compete in a highly competitive market. Forcing Defendants to reveal highly-sensitive business information to their competitors would serve only to hamper the flow of discovery and the efficient resolution of these Actions. Moreover, Defendants collectively produced millions of pages of competitively sensitive information in reliance on the

Protective Order. If this Court adopts Plaintiffs' rationale, whereby some confidential documents are less confidential than others, the Court will render its own Protective Order moot and create confusion resolvable only through further motion practice. *See, e.g.*, *Rutigliano v. Appleton Papers, Inc.*, No. 90-1432, 2000 WL 1705152 at *5 (D.N.J. Oct. 6, 2000) (public disclosure in product liability action should not be compelled where defendant produced material in reliance on a confidentiality order).

III. CONCLUSION

For the foregoing reasons and those asserted in its Motion to Seal, ZHP respectfully requests that the court grant the Motion to Seal. Alternatively, in the event the Court determines that there is an overriding public interest in having non-confidential portions of the documents Plaintiffs seek to unseal, the ZHP Parties request the opportunity to propose redacted versions of the documents sought to be sealed in order to protect the portions of the proposed sealed documents that are entitled to confidentiality.

Dated: March 8, 2021

Respectfully submitted,

/s/ Seth A. Goldberg
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CERTIFICATE OF SERVICE

I, Kelly A. Bonner Esq., hereby certify that a complete copy of the foregoing ZHP Parties' Reply Brief in Support of Their Motion to Seal have been filed electronically on the docket for this matter and are available for viewing and downloading from the ECF system. These documents are being served upon the following counsel on March 8, 2021 through the ECF system, and a courtesy copy is being sent by email:

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